composition. This claim uses the identical topical patented pharmaceutical composition as recited in claim 1 of U.S. Patent 5,888,984. Clearly, since the topical pharmaceutical composition recited in claim 1 of U.S. Patent 5,888,984 is novel and non-obvious over the prior art relied upon by the Examiner, the claimed new use of the same composition must be patentable for the same reasons.

Claim 29 relates to a method for effecting transdermal migration of a macromolecule comprising applying a pharmaceutical composition to an area of skin of a mammal. This claim uses the identical patented topical pharmaceutical composition as recited in claim 19 of U.S. Patent 5,888,984. Clearly, since the pharmaceutical composition recited in claim 19 of U.S. Patent 5,888,984 is novel and non-obvious over the prior art relied upon by the Examiner, the claimed new use of the same composition must be patentable for the same reasons.

Claim 30 recites a method for promoting granulation of wounds comprising applying directly to said wound a pharmaceutical composition. This claim uses the identical patented pharmaceutical composition as recited in claim 19 of U.S. Patent 5,888,984. Clearly, since the topical pharmaceutical composition recited in claim 19 of U.S. Patent 5,888,984 is novel and non-obvious over the prior art relied upon by the Examiner, the claimed new use of the same composition must be patentable for the same reasons.

This issue was discussed during the interview of July 16, 2002. This point was acknowledged by the Examiner's supervisor during the interview of July 16, 2002. Therefore, an indication of allowance of claims 27-30 is respectfully requested. If the Examiner agrees with Applicants' representative and his supervisor in this regard, then the Examiner is respectfully requested to contact the undersigned prior to issuance of any future Office communications. At that point, Applicants will consider adding similar dependent claims on claims 27-30 as in the issued grand-parent. Such claims have not been added at this time in order to reduce costs for a small entity.

Rejection of Claims 1-26 Under 35 U.S.C. 102(e) over Lowry

Claims 1-26 have been rejected by the Examiner as being anticipated under 35 U.S.C. 102(e) by U.S. Patent 4,900,550 to Lowry for the reasons set forth on page 3 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner is respectfully requested to specifically refer to the column and line number of the Lowry patent which teaches any composition useful in either of the following methods:

1. A method of transdermal migration of a macromolecule (e.g. claims 1, 2, 4, 5, 7, 8, 11-27 and 29); and
2. A method of promoting granulation of wounds (e.g. claims 3, 6, 9, 10, 28 and 30).

In each of the Office Actions of record, the Examiner has failed to specifically point to any teaching relating to the recited methods. As such, the Examiner has twice failed to comply with Rule 104, part (c)(2). Even if the composition per se was known in the art, which is a point not conceded by Applicants, the Examiner fails to recite any particular part of the reference which teaches that the claimed methods of use are known.

In Paper number 7, the most the Examiner states on the subject is that "Lowry discloses the use of several different types of macromolecules and complex carbohydrates in combination with essential oils which is readable upon the scope of the applicants claims." However, Applicants claim new methods of use rather than compounds or compositions per se. The mere existence of a compound or composition does not destroy the novelty of uses which are not even disclosed in the reference. In this case, the cited reference is deficient in failing to disclose both the new use(s) as well as the composition being used. The Examiner should be specific by referring to the column and line number of the Lowry reference which supports a position relevant to the claimed invention. Otherwise, the rejection is moot.

Notwithstanding the interview with the Examiner and his supervisor last July, the Examiner again states in Paper 10 that "Lowry discloses...combination...which is readable upon the scope of the applicants claims." However, the Examiner again fails to recognize that Applicants are claiming novel and nonobvious uses for a composition that is not even disclosed in the prior art. The Examiner again fails to specifically refer to the column and line number of the Lowry reference which supports his position.

Since the Examiner fails to refer to any portion of the Lowry reference expressly teaching the claimed novel uses of a pharmaceutical composition including a method of transdermal migration of a macromolecule and a method of promoting granulation of wounds, the anticipation rejection must fail.

Applicants further note the Examiner's comments in item 2 on page 5 of the Office Action. Applicants have amended claims 1, 3 and 11 in the manner suggested by the Examiner in order to expedite prosecution or reduce issues on appeal. However, the limitation in question does not further limit or remotely narrow the scope of the claims. There is absolutely no difference between "a pharmaceutical composition" and "a pharmaceutically effective composition". This amendment is presented to merely reduce costs for a small entity concerning an issue that may lead to an unnecessary appeal with respect to what amounts to be a matter of semantics. These phrases mean the same thing. No new matter has

been added. This is clearly intended to be a non-narrowing claim amendment.

The rejection of claims 1-26 as being anticipated under 35 U.S.C. 102(e) by U.S. Patent 4,900,550 to Lowry is overcome in view of the amendments of record (i.e. pharmaceutical composition). This issue is similar to the issue in the grandparent application (U.S. Patent 5,888,984) and the rejection should be withdrawn for the same reasons.

Briefly, Applicants' representative maintains that with respect to the Lowry reference, there is no anticipation or *prima facie* case of obviousness since the ingredients in the Lowry reference are not present in a pharmaceutically effective amount and because the claimed use is nowhere disclosed in Lowry. Applicants' position is supported by the testing of record which show that even higher amounts of the ingredients described in the cosmetic composition of the Lowry reference do not produce the pharmaceutical effect of relieving pain, inflammation or itching. As a result, it is readily apparent that the lower amounts of the ingredients of the Lowry reference would also not contain pharmaceutically effective amounts of the active ingredient and effective amounts of the essential oil in order to obtain the claimed method of use of the pharmaceutical composition.

Lowry discloses topical cosmetic compositions and uses thereof as a cosmetic. However, none of the claims of the present

invention are directed to the uses of cosmetic compositions. Rather, all of the claims of the present invention are directed to methods using pharmaceutical compositions. A pharmaceutical composition is useful, for example, for treating inflammation, pain or itching. Cosmetic preparations are not useful for treating anything. The term "pharmaceutical composition" is not a "cosmetic composition". Moreover, Applicant's novel use (i.e. method claim(s)) is clearly not taught by Lowry. Thus, there is no anticipation.

The definition of "pharmaceutical" according to the Random House Dictionary of the English language, page 1079, is a "pharmaceutical preparation, drug..." The definition of "cosmetic" according to the Random House Dictionary of the English language, page 329, is "a powder, lotion or other preparation for beautifying the complexion, skin,hair, nails, etc." It is clear that a cosmetic as described by Lowry is not a pharmaceutical as claimed. The terms "cosmetic" and "pharmaceutical" have well-accepted meanings in the art. The Examiner is ignoring the art-recognized definitions in making this rejection. Lowry does not disclose an effective amount of active ingredient for Applicant's use. Moreover, Lowry does not disclose the novel and non-obvious use of the claimed composition.

The Lowry reference does not anticipate or suggest the present invention because the use is not disclosed and/or because

the active ingredient is not present in a pharmaceutically effective amount. The Lowry reference does not anticipate or suggest the present invention since it discloses an amount of essential oil which is not sufficient to allow penetration of the dermis of mammals by the complex carbohydrate or the claimed use thereof.

The description in column 4, line 13 of the Lowry reference discloses that hyaluronic acid is present in an amount of 0.09-0.11 wt.%. The description in column 6, line 17 of Lowry et al. discloses that hyaluronic acid is present in an amount of 0.05-0.10 wt.%. The amount of hyaluronic acid disclosed in the Lowry reference is not a pharmaceutically effective amount when combined in the low amounts of essential oil disclosed in Lowry. In order to support Applicant's position, the Examiner's attention is again directed to the prior filed Declaration under 37 C.F.R. 1.132 which shows that when hyaluronic acid is used at a concentration below 0.3 wt.% when combined with 2% vol/vol tea tree oil, the composition will not have pain relieving effect. Thus, the lower amounts of hyaluronic acid and essential oil of the Lowry reference would be pharmaceutically ineffective and thus not fall within the scope of the present invention. However, the failure of Lowry to disclose the claimed use by itself renders the Examiner's rejection moot.

The Examiner should note that the Declaration in the response to the anticipation rejection is submitted to support an argument that the cosmetic compositions of the Lowry reference are not pharmaceutical compositions. Thus, there is no anticipation of the invention.

In column 3, line 8 of the Lowry reference, jojoba oil is said to be present in an amount of 0.18-0.22 wt.%. In column 3, line 67 of the Lowry reference, sweet almond oil is said to be present in an amount of 0.09-0.11 wt.%. In column 6, line 8, jojoba oil is said to be present in an amount of 0.1-0.03 wt.%. Therefore, the composition of the Lowry reference cannot be said to anticipate the claimed invention, because it does not disclose or suggest effective amounts of the claimed ingredients for the claimed function(s). Moreover, the Lowry reference nowhere discloses the claimed uses.

Finally, the Examiner's comments in item (1) on page 5 of the Office Action appear to be technically inaccurate. For example, claim 4 recites that the essential oil in the composition is present in an amount of 0.5 to 20% vol/vol. The Examiner alleges that this claimed range overlaps with a range of 0.09-0.11 wt%. Clarification of how these ranges overlap is respectfully requested.

In summary, the Lowry reference does not anywhere disclose the claimed method of uses with any composition. Alternatively, the Lowry composition contains hyaluronic acid below 0.3 wt.% and essential oil below 2% vol/vol. Therefore, the cosmetic Lowry compositions are not inherently pharmaceutically effective. Thus, the Lowry reference does not anticipate or suggest the present invention.

Rejection of Claims 1-26 Under 35 U.S.C. 103(a) over Lowry In View of Williams et al.

Claims 1-26 are rejected by the Examiner under 35 U.S.C. 103(a) over Lowry in view of Williams et al. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The above-mentioned comments with respect to the Lowry reference are herein incorporated by reference.

Briefly, the Lowry reference is directed to a cosmetic composition. There is no motivation for modifying the teachings thereof and converting the cosmetic composition thereof into a pharmaceutical composition. Moreover, the claimed method of uses are nowhere disclosed in the Lowry reference.

Furthermore, modifying the cosmetic composition of the Lowry reference into a pharmaceutical composition would destroy the teachings thereof. Such hindsight is not allowed. See MPEP 2143 at page 2100-124 (August 2001) and In re Gordon, 221 USPQ USPQ 1125

(Fed. Cir. 1984).

Despite the fact that the MPEP and precedential case law caution the Examiner from making rejections which destroy the teaching of the primary reference in order to obtain the present invention, the Examiner utilizes Applicants' specification as a roadmap and relies on a secondary reference in an attempt to suggest the present invention. Such hindsight is not allowed.

The Lowry reference provides no motivation for carrying any active ingredient transdermally or for promoting the granulation of wounds. The Examiner, recognizing this deficiency, relies on a secondary reference. Transdermal delivery is the subject of the Williams reference. Ignoring the fact that there is no motivation to combine the teachings of these references, the Examiner's position is that since it is known to use essential oils as penetration enhancers towards 5-fluorouracil, then why not use such enhancers for cosmetics? However, 5-fluorouracil is a drug for battling cancer. No other drugs are suggested. And even if other drugs were suggested by the Williams reference, the Examiner should recall that the Lowry reference has nothing to do with delivering drugs. Therefore, there is no motivation for combining the teachings of theses two references in order to obtain the present invention. Alternatively, combining the teachings of these two references in the manner suggested by the Examiner would destroy the teachings of the primary Lowry reference.

Accordingly, in view of the remarks hereinabove, combining the references in the manner suggested by the Examiner does not establish a prima facie case of obviousness. Thus, the rejection should be withdrawn.

Allowance of all claims is respectfully requested.

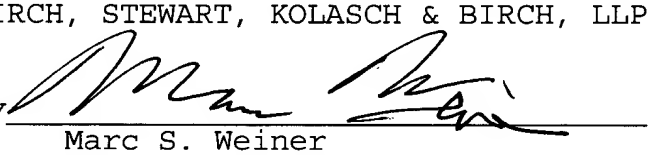
If the Examiner has any questions concerning this application, he is requested to contact the undersigned at (703) 205-8000 in the Washington, D.C. area.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a two month extension of time for filing a reply in connection with the present application, and the required fee of $205.00 is attached hereto

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

A paragraph has been added before the paragraph beginning on page 1, line 5.

IN THE CLAIMS

The claims have been amended as follows:

Claim 1 (Amended) A method for effecting transdermal migration of a macromolecule comprising combining a pharmaceutically effective amount of said macromolecule in a [pharmaceutical] pharmaceutically effective composition with an amount of an essential oil effective to promote transdermal migration of said macromolecule to obtain a mixture of said [pharmaceutical] pharmaceutically effective composition and applying said mixture of said [pharmaceutical] pharmaceutically effective composition to an area of skin of a mammal.

Claim 3 (Amended) A method for promoting granulation of wounds comprising applying directly to said wound a [pharmaceutical] pharmaceutically effective composition comprising a pharmacologically active amount of at least one complex carbohydrate and at least one essential oil in an amount effective to provide penetration of the dermis of a mammal of the complex carbohydrate.

Claim 11 (Amended) A method for effecting transdermal migration of a [pharmaceutical] pharmaceutically effective composition comprising applying said [pharmaceutical] pharmaceutically effective composition to the skin of a mammal, said [pharmaceutical] pharmaceutically effective composition comprising at least one complex carbohydrate of low purity or cosmetic grade and an essential oil in an amount effective to provide transdermal migration of said [pharmaceutical] pharmaceutically effective composition.

Claims 27-30 are added.